Name: **Enrolment No:**	

UPES

End Semester Examination, May 2025

Course: Clinical Monitoring **Semester: VI**

Program: BSc Clinical Research **Duration: 3 Hours**

Course Code: HSCR3006P **Max. Marks: 100**

Instructions: Attempt all the Sections

S. No.	Section A **Short answer questions/ MCQ/T&F (20Qx1.5M= 30 Marks)**	Marks	COs
Q 1	Which of the following statements is TRUE regarding EDC systems in clinical trials? a) EDC systems are optional and rarely used b) EDC systems reduce transcription errors compared to paper CRFs c) EDC systems do not require validation d) EDC systems are not accepted by regulatory authorities	**1.5**	**CO1**
Q 2	What is the primary goal of the Paperwork Reduction Act of 1995? a) Increase patient enrollment b) Reduce paperwork burden on individuals, businesses, and government c) Promote paper-based documentation d) Increase sponsor monitoring costs	**1.5**	**CO2**
Q 3	Which of the following is an essential element to consider when selecting an investigative site? a) Availability of luxury accommodation b) Proximity to sponsor's office c) Infrastructure to handle protocol requirements d) Access to shopping centers	**1.5**	**CO1**
Q 4	Define "Risk Based Monitoring in Clinical Trials".	**1.5**	**CO2**
Q 5	Failure to train site staff during initiation can lead to: a) Improved compliance b) Higher recruitment rates c) Increased protocol deviations and data errors d) Faster regulatory approval	**1.5**	**CO3**
Q 6	Who is responsible for providing training to investigators and site staff? a) Ethics committee b) Study participants c) Sponsor or Clinical Research Organization (CRO) d) Data Safety Monitoring Board	**1.5**	**CO1**

Q 7	Which of the following best describes source documentation in clinical trials? a) A sponsor's marketing report b) External literature review c) Original records where trial data are first recorded d) Budget summary sheets	**1.5**	**CO2**
Q 8	Which party is typically responsible for conducting the site initiation visit? a) Ethics committee b) Data analyst c) Monitor or CRA assigned by the sponsor/CRO d) Statistician	**1.5**	**CO3**
Q 9	Source Data Verification is the process of comparing trial data with _____.	**1.5**	**CO1**
Q 10	In on-site monitoring, the monitor visits the _____ to verify compliance.	**1.5**	**CO2**
Q 11	**True or False:** Monitoring plan amendments should be based only on increasing visit frequency.	**1.5**	**CO1**
Q 12	Define protocol deviation in clinical trials.	**1.5**	**CO2**
Q 13	Mention one key feature of an EDC system that ensures data security.	**1.5**	**CO3**
Q 14	**True or False:** Quality monitoring ensures trial integrity by detecting and correcting critical issues.	**1.5**	**CO2**
Q 15	Mention any two advantages of remote monitoring in clinical trials.	**1.5**	**CO1**
Q 16	Define case report form.	**1.5**	**CO1**
Q 17	Name one commonly used Electronic Data Capture (EDC) system.	**1.5**	**CO2**
Q 18	State any one reason why investigator training is essential.	**1.5**	**CO3**
Q 19	**True or False:** Risk-based monitoring focuses on data critical to participant safety and trial integrity.	**1.5**	**CO1**
Q 20	In terms of data quality, what does "data query" in an EDC system refer to? a) A system error b) A question raised to clarify data inconsistencies c) A final data summary d) A type of form	**1.5**	**CO2**
Section B **(4Qx5M=20 Marks)**			
Q 1	Mention the most important factors considered when selecting a site for clinical investigation.	**5**	**CO1**
Q 2	Evaluate the role of continuous investigator training and communication in enhancing protocol adherence and ensuring regulatory compliance during multicenter trials.	**5**	**CO2**
Q 3	Analyze how proper documentation supports quality assurance processes and regulatory submissions, ensuring trial credibility and compliance.	**5**	**CO3**
Q 4	Compare and contrast centralized monitoring with traditional on-site monitoring in clinical trials.	**5**	**CO2**
Section C **(2Qx15M=30 Marks)**			

Q 1	Background: A medical device company is conducting a clinical trial to evaluate the effectiveness of a new wearable glucose monitoring system for patients with type 2 diabetes. The trial is being conducted at 20 sites across different countries. Given the complexity of managing large-scale patient data and ensuring proper device usage, the company has implemented a risk-based monitoring strategy. The focus is on monitoring patient adherence to the device usage and ensuring data accuracy, especially in sites with previous issues with data entry. Scenario: Centralized monitoring of eCRFs reveals that two sites have a higher incidence of incomplete data entries regarding blood glucose levels and instances where patients have failed to use the device as instructed. One of the sites also reported a higher-than-expected number of adverse events due to the malfunctioning of the device. The sponsor decides to allocate more resources to these high-risk sites for more frequent on-site monitoring and to investigate further the device-related issues and adherence discrepancies. Questions A. Develop an action plan to mitigate the risks associated with device adherence and data accuracy, including corrective measures. (5 Marks) B. Discuss how risk-based monitoring allows for targeted interventions and resource allocation based on the risks identified. (5 Marks) C. Prepare a monitoring plan that implements a risk-based approach for addressing the challenges in this clinical trial. (5 Marks)	**15**	**CO4**
Q 2	Background: A pharmaceutical company is conducting a phase III clinical trial to evaluate the efficacy and safety of a novel immunotherapy drug for treating metastatic lung cancer. The trial involves 25 study sites across various countries, with a total of 500 participants. The study aims to assess overall survival, progression-free survival, and the occurrence of immune-related adverse events. The company has decided to implement a risk-based monitoring (RBM) approach to efficiently allocate resources and address potential risks associated with participant safety and protocol adherence. Scenario: During the monitoring of the clinical trial, the following challenges and risks were identified: Discrepancies in Adverse Event Reporting: At three high-risk sites, there are delays and inconsistencies in the reporting of immune-related adverse events. The site staff is struggling with the complexity of the adverse event criteria, leading to underreporting and incorrect documentation. Data Quality Issues with Tumor Assessments: The data entered in the electronic case report forms (eCRFs) at one site do not match the source documents regarding tumor size measurements. Some sites are failing to upload the required imaging data in a timely manner, which affects the accuracy of the progression-free survival assessments.	**15**	**CO5**

	Patient Non-Adherence to Treatment Protocol: There are reports from one site where several participants have not adhered to the investigational treatment schedule, with doses missed or delayed. This non-adherence may impact the study's primary endpoints. Questions Ques 1. Develop an action plan to address the identified challenges in adverse event reporting, data quality, patient adherence. (5 Marks) Ques 2. Explain how risk-based monitoring can help prioritize these challenges and improve site performance. (5 Marks) Ques 3. Prepare a monitoring plan based on risk-based monitoring strategies to address these challenges, including additional site visits, training sessions, and data verification processes. (5 Marks)		
Section D (2Qx10M=20 Marks)			
Q 1	Examine the importance of clinical investigator training and ongoing communication in clinical trials. How do these factors contribute to protocol adherence and overall trial quality?	**5+5**	**CO3**
Q 2	Explain the role of documentation in monitoring clinical trials. How does effective documentation ensure regulatory compliance and the maintenance of data integrity throughout the trial process?	**5+5**	**CO4**